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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,519

03/03/2006

Hilary Clark

P1984R1

2294

9157 7590 02/29/2008
GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

02/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,519	Applicant(s) CLARK ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 and 16-27 have been cancelled. Claims 10-15 have been amended to be directed to SEQ ID NO: 591 and 592.

Specification

A substitute specification is again required pursuant to 37 CFR 1.125(a) because the font size of the specification is too small and cannot be easily read. See MPEP 608.01 concerning appropriate font sizes and styles.

This requirement was set forth in the restriction requirement but not addressed in the response filed 11/20/07. Failure to submit an appropriate substitute specification will be held non-responsive.

The description portion of this application contains a computer program listing consisting of more than three hundred (300) lines. In accordance with 37 CFR 1.96(c), a computer program listing of more than three hundred lines must be submitted as a computer program listing appendix on compact disc conforming to the standards set forth in 37 CFR 1.96(c)(2) and must be appropriately referenced in the specification (see 37 CFR 1.77(b)(5)). **Accordingly, applicant is required to cancel the computer program listing appearing in the specification on pages 49-65, file a computer program listing appendix on compact disc in compliance with 37 CFR 1.96(c) and insert an appropriate reference to the newly added computer program listing appendix on compact disc at the beginning of the specification.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "a polypeptide encoded by the full length coding region of the nucleotide sequence of SEQ ID NO: 591." This is confusing as SEQ ID NO: 591 is 3775 nucleotides and contains non-coding sequence with respect to polypeptide SEQ ID NO: 592. The only polypeptide disclosed as being encoded by SEQ ID NO: 591 is SEQ ID NO: 592. It is unclear whether the claims embrace another polypeptide encoded by SEQ ID NO: 591, and if so, what the identity of the polypeptide is.

Claim 14 is indefinite in reciting a "therapeutically effective amount." The claim does not recite any intended therapy and as such it cannot be determined what amounts of antibody would be therapeutic and meet the limitations of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (U.S. Patent No. 6,812,339).

SEQ ID NO: 592 of the instant application is a 592 amino acid human sequence. SEQ ID NO: 7289 of Venter et al. has greater than 80% amino acid identity to instant SEQ ID NO: 2. Venter et al. discloses producing antibodies that specifically bind to SEQ ID NO: 7289, including monoclonal antibodies. Venter et al. also discloses pharmaceutical compositions with labels. See at least SEQ ID NO: 7289, columns 6, 13-14, and 30.

With respect to claim 15, the antibodies of Venter et al. would have been in a container, particularly in the context of the pharmaceutical compositions. Standard procedure would have resulted in some identifying information (i.e. label) on the container. Applicant is reminded that intended use language such as “can be used for treating an immune related disease” is given no patentable weight in a product claim. *In re Heller*, 73 USPQ 403, makes clear that application of printed matter to a known article cannot render the article patentable. It does not make it a new or different composition.

Alignment of instant SEQ ID NO: 592 with SEQ ID NO: 7289 of Venter et al.:

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US-09-949-016-7289
; Sequence 7289, Application US/09949016
; Patent No. 6812339
; GENERAL INFORMATION:
; APPLICANT: VENTER, J. Craig et al.
; TITLE OF INVENTION: POLYMORPHISMS IN KNOWN GENES ASSOCIATED
; TITLE OF INVENTION: WITH HUMAN DISEASE, METHODS OF DETECTION AND USES
THEREOF
; FILE REFERENCE: CL001307
; CURRENT APPLICATION NUMBER: US/09/949,016
; CURRENT FILING DATE: 2000-04-14
; PRIOR APPLICATION NUMBER: 60/241,755
; PRIOR FILING DATE: 2000-10-20
; PRIOR APPLICATION NUMBER: 60/237,768
; PRIOR FILING DATE: 2000-10-03
; PRIOR APPLICATION NUMBER: 60/231,498
; PRIOR FILING DATE: 2000-09-08
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; NUMBER OF SEQ ID NOS: 207012
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 7289
; LENGTH: 452
; TYPE: PRT
; ORGANISM: Human
US-09-949-016-7289
```

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Query Match          99.7%; Score 1763; DB 2; Length 452;
Best Local Similarity 100.0%; Pred. No. 2.5e-132;
Matches 337; Conservative 0; Mismatches 0; Indels 0; Gaps
0;
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Qy      1 MFQAFPGDYDSGSRCSSSPSAESQYLSSVDSFGSPPTAAASQECAGLGEMPGSFVPTVTA 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      115 MFQAFPGDYDSGSRCSSSPSAESQYLSSVDSFGSPPTAAASQECAGLGEMPGSFVPTVTA
174
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Qy      61 ITTSQDLQWLQPTLISSMAQSQGQPLASQPPVDPYDMPGTSYSTPGMSGYSSGGASGS
120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      175 ITTSQDLQWLQPTLISSMAQSQGQPLASQPPVDPYDMPGTSYSTPGMSGYSSGGASGS
234
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Qy      121 GGPSTSGTTS GPGPARPARARPRRPREETLTPEEEEEKRRVRRERNKLAAAKCRNRRRELT
180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      235 GGPSTSGTTS GPGPARPARARPRRPREETLTPEEEEEKRRVRRERNKLAAAKCRNRRRELT
294
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Qy      181 DRLQAETDQLEEEKAELESEIAELQKEKERLEFVLVAHKPGCKIPYEEGPGPGPLAEVRD
240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      295 DRLQAETDQLEEEKAELESEIAELQKEKERLEFVLVAHKPGCKIPYEEGPGPGPLAEVRD
354
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Qy      241 LPGSAPAKEDGFSWLLPPPPPPPLPFQTSQDAPPNLTASLFTHSEVQVLGDPFPVNPVS
300
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      355 LPGSAPAKEDGFSWLLPPPPPPPLPFQTSQDAPPNLTASLFTHSEVQVLGDPFPVNPVS
414
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Qy      301 TSSFVLTCPEVSAFAGAQR TSGSDQPSDPLNPSLLA 337
          ||||||||||||||||||||||||||||||||
Db      415 TSSFVLTCPEVSAFAGAQR TSGSDQPSDPLNPSLLA 451
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Claims 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Verma et al.
(U.S. Patent No. 5,470,736).

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SEQ ID NO: 592 of the instant application is a 592 amino acid human sequence. SEQ ID NO: 2 of Verma et al. has greater than 80% amino acid identity to instant SEQ ID NO: 2. Verma et al. discloses producing antibodies that specifically bind to SEQ ID NO: 2, including monoclonal antibodies. Verma et al. also discloses compositions. See at least SEQ ID NO: 2, column 6, and the claims.

With respect to claim 15, the antibodies of Verma et al. would have been in a container, particularly in the context of the pharmaceutical compositions. Standard procedure would have resulted in some identifying information (i.e. label) on the container. Applicant is reminded that intended use language such as “can be used for treating an immune related disease” is given no patentable weight in a product claim. *In re Heller*, 73 USPQ 403, makes clear that application of printed matter to a known article cannot render the article patentable. It does not make it a new or different composition.

Alignment of instant SEQ ID NO: 592 with SEQ ID NO: 2 of Verma et al.:

US-08-218-686-2
; Sequence 2, Application US/08218686
; Patent No. 5470736
; GENERAL INFORMATION:
; APPLICANT: Verma Ph.D., Inder M.
; APPLICANT: Wisdom M.D., Ronald M.
; APPLICANT: Yen Ph.D., Jong-Young J.
; TITLE OF INVENTION: TRANSDOMINANT NEGATIVE PROTO-ONCOGENE
; NUMBER OF SEQUENCES: 2
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Spensley Horn Jubas & Lubitz
; STREET: 4225 Executive Square, Suite 1400
; CITY: La Jolla
; STATE: CA
; COUNTRY: US
; ZIP: 92037
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:

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; APPLICATION NUMBER: US/08/218,686
; FILING DATE:
; CLASSIFICATION: 435
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 07/710,862
; FILING DATE: 10-JUN-1991
; ATTORNEY/AGENT INFORMATION:
; NAME: Wetherell, Jr. Ph.D., John R.
; REGISTRATION NUMBER: 31,678
; REFERENCE/DOCKET NUMBER: PD-1323
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (619) 455-5100
; TELEFAX: (610) 455-5110
; INFORMATION FOR SEQ ID NO: 2:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 338 amino acids
; TYPE: amino acid
; TOPOLOGY: linear
; MOLECULE TYPE: protein
US-08-218-686-2
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Query Match          95.5%; Score 1689; DB 1; Length 338;
Best Local Similarity 95.8%; Pred. No. 1.4e-126;
Matches 323; Conservative 6; Mismatches 8; Indels 0; Gaps
0;
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Qy      1 MFQAFPGDYDSGSRCSSSPSAESQYLSSVDSFGSPPTAAASQECAGLGEMPGSFVPTVTA 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MFQAFPGDYDSGSRCSSSPSAESQYLSSVDSFGSPPTAAASQECAGLGEMPGSFVPTVTA 60

Qy      61 ITTSQDLQWLQPTLISSMAQSQGQPLASQPPVDPYDMPGTSYSTPGMSGYSSGGASGS
120
          ||||||||||||||||||||||||||||| |||||||||||||:| ||:|||||
Db      61 ITTSQDLQWLQPTLISSMAQSQGQPLASQPPAVDPYDMPGTSYSTPGLSAYSTGGASGS
120

Qy      121 GGPSTSGTTSGPGPARPARARPRRPREETLTPEEEEEKRRVRRERNKLAAAKCRNRRRELT
180
          ||||| ||||| ||||||||||||||||||||||||||||||||||||||||
Db      121 GGPSTSTTTSGPV SARPARARPRRPREETLTPEEEEEKRRVRRERNKLAAAKCRNRRRELT
180

Qy      181 DRLQAETDQLEEEKAELESEIAELQKEKERLEFVLVAHKPGCKIPYEEGPGPGPLAEVRD
240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      181 DRLQAETDQLEEEKAELESEIAELQKEKERLEFVLVAHKPGCKIPYEEGPGPGPLAEVRD
240

Qy      241 LPGSAPAKEDGFSWLLPPPPPPPLPFQTSQDAPPNLTASLFTHSEVQVLGDPFPVNP SY
300
          |||| ||||| |||||||||||||:|:|||||||||||:|||||
Db      241 LPGSTSAKEDGFGWLLPPPPPPPLPFQSSRDAPPNLTASLFTHSEVQVLGDPFPVSPSY
300
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Qy 301 TSSFVLTCPEVSAFAGAQR TSGSDQPSDPLNSP SLLA 337
 | | | | | | | | | | | | | | | | : | | | | | | | | | |
Db 301 TSSFVLTCPEVSAFAGAQR TSGSEQPSDPLNSP SLLA 337

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa